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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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<210> 658

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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&lt;211&gt; 7

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&lt;400&gt; 673

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&lt;210&gt; 674

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 674

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&lt;210&gt; 675

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 675

Asp Thr Phe Lys Gln Ser Ser

1

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&lt;210&gt; 676

&lt;211&gt; 7

&lt;212&gt; PRT

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&lt;220&gt;

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&lt;400&gt; 676

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&lt;210&gt; 677

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<210> 680

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<210> 681

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&lt;210&gt; 682

&lt;211&gt; 7

&lt;212&gt; PRT

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antibody and further modified by amino acid  
substitutions

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Asp Thr Phe Gly Leu Ala Ser  
1 5

&lt;210&gt; 683

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 683

Asp Thr Phe Gly Leu Ser Ser  
1 5

&lt;210&gt; 684

&lt;211&gt; 7

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antibody and further modified by amino acid  
substitutions

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Asp Thr Phe Gly Leu Lys Ser  
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&lt;210&gt; 685

&lt;211&gt; 7

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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<210> 693

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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<210> 707

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substitutions

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antibody and further modified by amino acid  
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<210> 709

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antibody and further modified by amino acid  
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<210> 710

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substitutions

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antibody and further modified by amino acid  
substitutions

<400> 711

Asp Thr Phe Arg Leu Pro Ser  
1 5

<210> 712  
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antibody and further modified by amino acid  
substitutions

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<210> 713  
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antibody and further modified by amino acid  
substitutions

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<210> 714  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

<400> 715  
Asp Thr Phe Arg His Ser Ser  
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<210> 717

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<210> 718

<211> 7

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<400> 718

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<210> 719

<211> 7

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<210> 720

<211> 7

<212> PRT

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<210> 721

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antibody and further modified by amino acid  
substitutions

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<210> 722

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 723

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 724

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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<210> 725  
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<220>  
<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 725  
Asp Thr Phe Arg Gln Arg Ser  
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<210> 726  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 729  
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<210> 730

<211> 7

<212> PRT

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<210> 731

<211> 7

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<210> 732

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<210> 733

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<210> 734

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 736

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antibody and further modified by amino acid  
substitutions

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1 5

<210> 737

<211> 7

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<220>

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antibody and further modified by amino acid  
substitutions

<400> 737

Asp Thr Phe Tyr His Ser Ser  
1 5

<210> 738

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antibody and further modified by amino acid  
substitutions

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1 5

<210> 739  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 743

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Asp Thr Phe Tyr His Asp Ser  
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<210> 744

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<210> 745

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<210> 746

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<210> 747

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<210> 748

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<210> 749

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<210> 750

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<210> 751

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antibody and further modified by amino acid  
substitutions

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<210> 752  
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antibody and further modified by amino acid  
substitutions

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<210> 753  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 756

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antibody and further modified by amino acid  
substitutions

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<210> 757

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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<210> 758

<211> 7

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 760

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 761

<211> 7

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antibody and further modified by amino acid  
substitutions

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Asp Thr Phe Phe His Lys Ser  
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<210> 762

<211> 7

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antibody and further modified by amino acid  
substitutions

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Asp Thr Phe Phe His Arg Ser  
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<210> 763

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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Asp Thr Phe Phe His His Ser  
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<210> 764

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<210> 765  
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<210> 766  
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<210> 769

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<210> 770

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<210> 772

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 776

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 782

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antibody and further modified by amino acid  
substitutions

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<210> 783

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antibody and further modified by amino acid  
substitutions

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<210> 784

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antibody and further modified by amino acid  
substitutions

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<210> 785

<211> 7

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antibody and further modified by amino acid  
substitutions

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&lt;210&gt; 786

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 786

Asp Thr Phe Leu His Arg Ser

1

5

&lt;210&gt; 787

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 787

Asp Thr Phe Leu His His Ser

1

5

&lt;210&gt; 788

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 788

Asp Thr Phe Leu His Pro Ser

1

5

&lt;210&gt; 789

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 789

Asp Thr Phe Leu His Thr Ser

1

5

&lt;210&gt; 790

&lt;211&gt; 7

&lt;212&gt; PRT



<213> Artificial Sequence

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<210> 791

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<210> 792

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<400> 793

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1 5

<210> 794

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## substitutions

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&lt;210&gt; 795

&lt;211&gt; 7

&lt;212&gt; PRT

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

&lt;400&gt; 795

Asp Thr Phe Leu Gln His Ser  
1 5

&lt;210&gt; 796

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 796

Asp Thr Phe Leu Gln Pro Ser  
1 5

&lt;210&gt; 797

&lt;211&gt; 7

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 797

Asp Thr Phe Leu Gln Thr Ser  
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&lt;210&gt; 798

&lt;211&gt; 7

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&lt;213&gt; Artificial Sequence

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 798

Asp Thr Phe Leu Gln Asp Ser  
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<210> 802  
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<210> 803  
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<210> 804

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<210> 805

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<210> 818

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<210> 824

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<210> 825

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<210> 826

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<210> 827

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<210> 829

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<210> 835

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<210> 836

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<210> 837

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<210> 838  
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<210> 843  
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<210> 844  
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<210> 845  
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<210> 846  
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<210> 847

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<210> 848

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antibody and further modified by amino acid  
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<210> 849

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antibody and further modified by amino acid  
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<210> 850

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<210> 851  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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<210> 854  
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antibody and further modified by amino acid  
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<210> 855  
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<210> 856

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<210> 857

<211> 7

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<210> 858

<211> 7

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<210> 859

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<210> 860

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antibody and further modified by amino acid  
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<210> 861

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antibody and further modified by amino acid  
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<210> 862

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antibody and further modified by amino acid  
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<210> 863

<211> 7

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antibody and further modified by amino acid  
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<210> 864

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<210> 865  
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<210> 866  
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<210> 867  
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<210> 868  
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<210> 869

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<210> 870

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<210> 871

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<210> 872

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<210> 873

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antibody and further modified by amino acid  
substitutions

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<210> 874

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antibody and further modified by amino acid  
substitutions

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<210> 875

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antibody and further modified by amino acid  
substitutions

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<210> 876

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antibody and further modified by amino acid  
substitutions

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<210> 877

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<210> 878  
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<210> 879  
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<210> 880  
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<210> 881  
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antibody and further modified by amino acid  
substitutions

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<210> 882

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antibody and further modified by amino acid  
substitutions

<400> 882

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1 5

<210> 883

<211> 7

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antibody and further modified by amino acid  
substitutions

<400> 883

Asp Thr Tyr Tyr His His Ser  
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<210> 884

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

<400> 884

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<210> 885

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 886

<211> 7

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antibody and further modified by amino acid  
substitutions

<400> 886

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<210> 887

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 888

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 889

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antibody and further modified by amino acid  
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<210> 890

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antibody and further modified by amino acid  
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<400> 890  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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<210> 898

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antibody and further modified by amino acid  
substitutions

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<210> 899

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antibody and further modified by amino acid  
substitutions

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<210> 900

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 902

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antibody and further modified by amino acid  
substitutions

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1

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&lt;210&gt; 913

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1

5

&lt;210&gt; 914

&lt;211&gt; 7

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&lt;213&gt; Artificial Sequence

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&lt;400&gt; 914

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1

5

&lt;210&gt; 915

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<210> 1006

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<210> 1007

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antibody and further modified by amino acid  
substitutions

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<210> 1008

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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<210> 1011

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antibody and further modified by amino acid  
substitutions

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&lt;212&gt; PRT

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1012

Asp Thr Arg Tyr Leu Thr Ser

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&lt;210&gt; 1013

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1013

Asp Thr Arg Tyr Leu Asp Ser

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&lt;210&gt; 1014

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1014

Asp Thr Arg Tyr His Ala Ser

1

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&lt;210&gt; 1015

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1015

Asp Thr Arg Tyr His Ser Ser

1

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&lt;210&gt; 1016

&lt;211&gt; 7

&lt;212&gt; PRT

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<211> 7

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<213> Artificial Sequence

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<211> 7

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<210> 1019

<211> 7

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<210> 1020

<211> 7

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substitutions

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<210> 1021

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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<210> 1025

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<210> 1026

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<210> 1028

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<210> 1029

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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<210> 1047

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antibody and further modified by amino acid  
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<210> 1048

<211> 7

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antibody and further modified by amino acid  
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<210> 1049

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antibody and further modified by amino acid  
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<210> 1050

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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<210> 1054

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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<210> 1062

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antibody and further modified by amino acid  
substitutions

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<210> 1063

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antibody and further modified by amino acid  
substitutions

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&lt;211&gt; 7

&lt;212&gt; PRT

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&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1064

Asp Thr Arg Leu His His Ser

1

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&lt;210&gt; 1065

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1065

Asp Thr Arg Leu His Pro Ser

1

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&lt;210&gt; 1066

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1066

Asp Thr Arg Leu His Thr Ser

1

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&lt;210&gt; 1067

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1067

Asp Thr Arg Leu His Asp Ser

1

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&lt;210&gt; 1068

&lt;211&gt; 7

&lt;212&gt; PRT



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<210> 1069

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<210> 1070

<211> 7

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Asp Thr Arg Leu Gln Lys Ser  
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<210> 1071

<211> 7

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Asp Thr Arg Leu Gln Arg Ser  
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<210> 1072

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antibody and further modified by amino acid  
substitutions

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1 5

<210> 1073

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antibody and further modified by amino acid  
substitutions

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<210> 1074

<211> 7

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antibody and further modified by amino acid  
substitutions

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Asp Thr Arg Leu Gln Thr Ser  
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<210> 1075

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 1076

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antibody and further modified by amino acid  
substitutions

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&lt;210&gt; 1077

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1077

Asp Thr Met Lys Leu Arg Ser

1

5

&lt;210&gt; 1078

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1078

Asp Thr Met Lys Leu His Ser

1

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&lt;210&gt; 1079

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1079

Asp Thr Met Lys Leu Pro Ser

1

5

&lt;210&gt; 1080

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1080

Asp Thr Met Lys Leu Thr Ser

1

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&lt;210&gt; 1081

&lt;211&gt; 7

&lt;212&gt; PRT

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<210> 1082

<211> 7

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<210> 1083

<211> 7

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<400> 1083

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<210> 1084

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<223> Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

<400> 1084

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<210> 1085

<211> 7

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&lt;210&gt; 1086

&lt;211&gt; 7

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&lt;213&gt; Artificial Sequence

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 1086

Asp Thr Met Lys His His Ser  
1 5

&lt;210&gt; 1087

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 1087

Asp Thr Met Lys His Pro Ser  
1 5

&lt;210&gt; 1088

&lt;211&gt; 7

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

&lt;400&gt; 1088

Asp Thr Met Lys His Thr Ser  
1 5

&lt;210&gt; 1089

&lt;211&gt; 7

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antibody and further modified by amino acid  
substitutions

&lt;400&gt; 1089

Asp Thr Met Lys His Asp Ser

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&lt;400&gt; 1129

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&lt;210&gt; 1130

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1130

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&lt;210&gt; 1131

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1131

Asp Thr Met Arg His His Ser

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&lt;210&gt; 1132

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&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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antibody and further modified by amino acid  
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&lt;210&gt; 1143

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&lt;213&gt; Artificial Sequence

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1143

Asp Thr Met Tyr Leu Lys Ser

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&lt;210&gt; 1144

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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&lt;210&gt; 1153

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

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&lt;210&gt; 1154

&lt;211&gt; 7

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

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&lt;210&gt; 1155

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&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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&lt;210&gt; 1156

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1156

Asp Thr Met Tyr His Asp Ser

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&lt;210&gt; 1157

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1157

Asp Thr Met Tyr Gln Lys Ser

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&lt;210&gt; 1158

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

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&lt;400&gt; 1194

Asp Thr Met Leu Leu Asp Ser

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&lt;210&gt; 1195

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1195

Asp Thr Met Leu His Ala Ser

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&lt;210&gt; 1196

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1196

Asp Thr Met Leu His Ser Ser

1

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&lt;210&gt; 1197

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1197

Asp Thr Met Leu His Lys Ser

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&lt;210&gt; 1198

&lt;211&gt; 7

&lt;212&gt; PRT

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<210> 1199

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
substitutions

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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Asp Thr Met Leu Gln Lys Ser  
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<210> 1206  
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antibody and further modified by amino acid  
substitutions

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Asp Thr Met Leu Gln Arg Ser



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&lt;210&gt; 1207

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1207

Asp Thr Met Leu Gln His Ser

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&lt;210&gt; 1208

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1208

Asp Thr Met Leu Gln Pro Ser

1

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&lt;210&gt; 1209

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1209

Asp Thr Met Leu Gln Thr Ser

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&lt;210&gt; 1210

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1210

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&lt;210&gt; 1211

&lt;211&gt; 7

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<210> 1212

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Asp Thr Lys Lys Leu Ser Ser  
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Asp Thr Lys Lys Leu Lys Ser  
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<210> 1214

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<210> 1215

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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&lt;212&gt; PRT

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1220

Asp Thr Lys Lys His Ser Ser

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&lt;210&gt; 1221

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1221

Asp Thr Lys Lys His Lys Ser

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&lt;210&gt; 1222

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1222

Asp Thr Lys Lys His Arg Ser

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&lt;210&gt; 1223

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1223

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&lt;210&gt; 1224

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<210> 1227

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<210> 1231  
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Asp Thr Lys Lys Gln Pro Ser  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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<210> 1237  
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Asp Thr Lys Gly Leu Arg Ser  
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Asp Thr Lys Gly Leu His Ser  
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<210> 1240  
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antibody and further modified by amino acid  
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<210> 1242

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antibody and further modified by amino acid  
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<210> 1243

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antibody and further modified by amino acid  
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<210> 1244

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antibody and further modified by amino acid  
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<210> 1245

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antibody and further modified by amino acid  
substitutions

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<210> 1246

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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Asp Thr Lys Gly His Arg Ser  
1 5

<210> 1247

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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Asp Thr Lys Gly His His Ser  
1 5

<210> 1248

<211> 7

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

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Asp Thr Lys Gly His Pro Ser  
1 5

<210> 1249

<211> 7

<212> PRT

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<220>

<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 1249

Asp Thr Lys Gly His Thr Ser  
1 5

<210> 1250

<211> 7

<212> PRT  
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<220>  
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1 5

<210> 1251  
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<400> 1251  
Asp Thr Lys Gly Gln Ala Ser  
1 5

<210> 1252  
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<212> PRT  
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Asp Thr Lys Gly Gln Ser Ser  
1 5

<210> 1253  
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<400> 1253  
Asp Thr Lys Gly Gln Lys Ser  
1 5

<210> 1254  
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antibody and further modified by amino acid  
substitutions

<400> 1254

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1 5

<210> 1255

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

<400> 1255

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1 5

<210> 1256

<211> 7

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antibody and further modified by amino acid  
substitutions

<400> 1256

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1 5

<210> 1257

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

<400> 1257

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1 5

<210> 1258

<211> 7

<212> PRT

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 1258

Asp Thr Lys Gly Gln Asp Ser

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&lt;210&gt; 1259

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1259

Asp Thr Lys Arg Leu Ala Ser

1

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&lt;210&gt; 1260

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1260

Asp Thr Lys Arg Leu Ser Ser

1

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&lt;210&gt; 1261

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1261

Asp Thr Lys Arg Leu Lys Ser

1

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&lt;210&gt; 1262

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1262

Asp Thr Lys Arg Leu Arg Ser

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&lt;210&gt; 1263

&lt;211&gt; 7

<212> PRT  
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1 5

<210> 1264  
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<400> 1264  
Asp Thr Lys Arg Leu Pro Ser  
1 5

<210> 1265  
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<212> PRT  
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Asp Thr Lys Arg Leu Thr Ser  
1 5

<210> 1266  
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<400> 1266  
Asp Thr Lys Arg Leu Asp Ser  
1 5

<210> 1267  
<211> 7  
<212> PRT  
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antibody and further modified by amino acid  
substitutions

<400> 1267

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1 5

<210> 1268

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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1 5

<210> 1269

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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1 5

<210> 1270

<211> 7

<212> PRT

<213> Artificial Sequence

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antibody and further modified by amino acid  
substitutions

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1 5

<210> 1271

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

<400> 1271

Asp Thr Lys Arg His His Ser

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&lt;210&gt; 1272

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1272

Asp Thr Lys Arg His Pro Ser

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&lt;210&gt; 1273

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1273

Asp Thr Lys Arg His Thr Ser

1

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&lt;210&gt; 1274

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1274

Asp Thr Lys Arg His Asp Ser

1

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&lt;210&gt; 1275

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1275

Asp Thr Lys Arg Gln Ala Ser

1

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&lt;210&gt; 1276

&lt;211&gt; 7

&lt;212&gt; PRT



<213> Artificial Sequence

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<223> Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

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<210> 1277

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<210> 1278

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<210> 1279

<211> 7

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substitutions

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antibody and further modified by amino acid  
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<210> 1282

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antibody and further modified by amino acid  
substitutions

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<210> 1283

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antibody and further modified by amino acid  
substitutions

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<210> 1284

<211> 7

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antibody and further modified by amino acid  
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&lt;211&gt; 7

&lt;212&gt; PRT

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&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1285

Asp Thr Lys Tyr Leu Lys Ser

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&lt;210&gt; 1286

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1286

Asp Thr Lys Tyr Leu Arg Ser

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&lt;210&gt; 1287

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1287

Asp Thr Lys Tyr Leu His Ser

1

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&lt;210&gt; 1288

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1288

Asp Thr Lys Tyr Leu Pro Ser

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&lt;210&gt; 1289

&lt;211&gt; 7

<212> PRT  
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<210> 1294

<211> 7

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<211> 7

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<210> 1296

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<210> 1298

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antibody and further modified by amino acid  
substitutions

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<210> 1299

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antibody and further modified by amino acid  
substitutions

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<210> 1300

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antibody and further modified by amino acid  
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<210> 1301

<211> 7

<212> PRT

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antibody and further modified by amino acid  
substitutions

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Asp Thr Lys Tyr Gln Lys Ser  
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<210> 1302

<211> 7

<212> PRT  
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antibody and further modified by amino acid  
substitutions

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<210> 1303  
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<220>  
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antibody and further modified by amino acid  
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<400> 1303  
Asp Thr Lys Tyr Gln His Ser  
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antibody and further modified by amino acid  
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<400> 1304  
Asp Thr Lys Tyr Gln Pro Ser  
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antibody and further modified by amino acid  
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<400> 1305  
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antibody and further modified by amino acid  
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<400> 1306

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<210> 1307

<211> 7

<212> PRT

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antibody and further modified by amino acid  
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Asp Thr Lys Phe Leu Ala Ser  
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<210> 1308

<211> 7

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antibody and further modified by amino acid  
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<210> 1309

<211> 7

<212> PRT

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antibody and further modified by amino acid  
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<210> 1310

<211> 7

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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
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antibody and further modified by amino acid  
substitutions

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<210> 1315  
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Asp Thr Lys Phe His Ala Ser  
1 5

<210> 1316  
<211> 7  
<212> PRT  
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<210> 1317  
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Asp Thr Lys Phe His Lys Ser  
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<210> 1318  
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Asp Thr Lys Phe His Arg Ser  
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antibody and further modified by amino acid  
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<210> 1320

<211> 7

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antibody and further modified by amino acid  
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<210> 1321

<211> 7

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antibody and further modified by amino acid  
substitutions

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Asp Thr Lys Phe His Thr Ser  
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<210> 1322

<211> 7

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<220>

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antibody and further modified by amino acid  
substitutions

<400> 1322

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<210> 1323

<211> 7

<212> PRT

<213> Artificial Sequence

<220>

<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 1323

Asp Thr Lys Phe Gln Ala Ser

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&lt;210&gt; 1324

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1324

Asp Thr Lys Phe Gln Ser Ser

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&lt;210&gt; 1325

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1325

Asp Thr Lys Phe Gln Lys Ser

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&lt;210&gt; 1326

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1326

Asp Thr Lys Phe Gln Arg Ser

1

5

&lt;210&gt; 1327

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1327

Asp Thr Lys Phe Gln His Ser

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&lt;210&gt; 1328

&lt;211&gt; 7

<212> PRT  
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<220>  
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antibody and further modified by amino acid  
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Asp Thr Lys Phe Gln Pro Ser  
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<210> 1329  
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<220>  
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antibody and further modified by amino acid  
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<210> 1330  
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antibody and further modified by amino acid  
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<210> 1331  
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antibody and further modified by amino acid  
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1 5

<210> 1332  
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antibody and further modified by amino acid  
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<210> 1333

<211> 7

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antibody and further modified by amino acid  
substitutions

<400> 1333

Asp Thr Lys Leu Leu Lys Ser  
1 5

<210> 1334

<211> 7

<212> PRT

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 1334

Asp Thr Lys Leu Leu Arg Ser  
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<210> 1335

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 1335

Asp Thr Lys Leu Leu His Ser  
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<210> 1336

<211> 7

<212> PRT

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<223> Amino acid sequence derived from Murine monoclonal  
antibody and further modified by amino acid  
substitutions

<400> 1336

Asp Thr Lys Leu Leu Pro Ser

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&lt;210&gt; 1337

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1337

Asp Thr Lys Leu Leu Thr Ser

1

5

&lt;210&gt; 1338

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1338

Asp Thr Lys Leu Leu Asp Ser

1

5

&lt;210&gt; 1339

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1339

Asp Thr Lys Leu His Ala Ser

1

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&lt;210&gt; 1340

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1340

Asp Thr Lys Leu His Ser Ser

1

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&lt;210&gt; 1341

&lt;211&gt; 7

&lt;212&gt; PRT

<213> Artificial Sequence

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<223> Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

<400> 1341

Asp Thr Lys Leu His Lys Ser  
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<210> 1342

<211> 7

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<220>

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Asp Thr Lys Leu His Arg Ser  
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<210> 1343

<211> 7

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<400> 1343

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<210> 1344

<211> 7

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<210> 1345

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substitutions

<400> 1345

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<210> 1346

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antibody and further modified by amino acid  
substitutions

<400> 1346

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<210> 1347

<211> 7

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antibody and further modified by amino acid  
substitutions

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<210> 1348

<211> 7

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antibody and further modified by amino acid  
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<210> 1349

<211> 7

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antibody and further modified by amino acid  
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<400> 1349

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&lt;210&gt; 1350

&lt;211&gt; 7

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&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1350

Asp Thr Lys Leu Gln Arg Ser

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5

&lt;210&gt; 1351

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1351

Asp Thr Lys Leu Gln His Ser

1

5

&lt;210&gt; 1352

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

&lt;400&gt; 1352

Asp Thr Lys Leu Gln Pro Ser

1

5

&lt;210&gt; 1353

&lt;211&gt; 7

&lt;212&gt; PRT

&lt;213&gt; Artificial Sequence

&lt;220&gt;

&lt;223&gt; Amino acid sequence derived from Murine monoclonal antibody and further modified by amino acid substitutions

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&lt;210&gt; 1354

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<400> 1354

Asp Thr Lys Leu Gln Asp Ser  
1 5

<210> 1355

<211> 7

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<400> 1355

Asp Thr Leu Lys Leu Ser Ser  
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<210> 1356

<211> 7

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<400> 1356

Asp Thr Leu Lys Leu Lys Ser  
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<210> 1357

<211> 7

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<400> 1357

Asp Thr Leu Lys Leu Arg Ser  
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<210> 1358

<211> 7

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<400> 1358

Asp Thr Leu Lys Leu His Ser  
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<210> 1359

<211> 7

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<400> 1359

Asp Thr Leu Lys Leu Pro Ser  
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<210> 1360

<211> 7

<212> PRT

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<400> 1360

Asp Thr Leu Lys Leu Thr Ser  
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<210> 1361

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<400> 1361

Asp Thr Leu Lys His Ala Ser  
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<210> 1362

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<400> 1363  
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<210> 1364  
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antibody and further modified by amino acid  
substitutions

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<210> 1365  
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antibody and further modified by amino acid  
substitutions

<400> 1365  
Asp Thr Leu Lys His His Ser  
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<210> 1366  
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antibody and further modified by amino acid  
substitutions

<400> 1366  
Asp Thr Leu Lys His Pro Ser  
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<210> 1367

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antibody and further modified by amino acid  
substitutions

<400> 1367  
Asp Thr Leu Lys His Thr Ser  
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<210> 1368  
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antibody and further modified by amino acid  
substitutions

<400> 1368  
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<210> 1369  
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<210> 1469

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<210> 1470

<211> 7

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<400> 1496  
Phe Gln Gly Ser Trp Tyr Pro Phe Thr  
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(22) International Filing Date: 23 June 2006 (23.06.2006)

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(71) Applicant (for all designated States except US): **MEDIM-MUME, INC.** [US/US]; One Medimmune Way, Gaithersburg, MD 20878 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **WEI, Ziping** [US/US]; 11102 Welland Street, North Potomac, MD 21136 (US). **TOUS, Guillermo, I.** [US/US]; 146 Barnsfield Court, Gaithersburg, MD 20878 (US). **SCHENERMAN, Mark** [US/US]; 1 Cornfield Court, Reisterstown, MD 21136 (US). **ALLAN, Christian, B.** [US/US]; 4401 Gregg Road, Brookeville, MD 20833 (US).

(74) Agents: **INSOGNA, Anthony, M.** et al.; **JONES DAY,** 222 East 41st Street, New York, NY 10017-6702 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

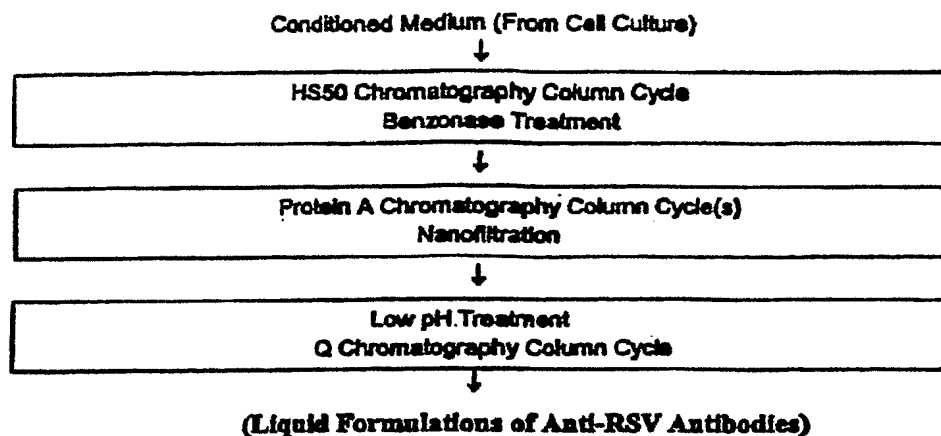
Published:

— with international search report  
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:  
19 July 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ANTIBODY FORMULATIONS HAVING OPTIMIZED AGGREGATION AND FRAGMENTATION PROFILES



(57) Abstract: The present invention provides methods of optimizing the production and purification of antibody formulations that immunospecifically bind to antigens of interest and are suitable for parenteral administration to a subject, which formulations exhibit increased stability due to reduced degradation and aggregation of the antibody component on long term storage. Such methods provide formulations that offer multiple advantages over formulations produced by non-optimized methods including less stringent or more readily available transportation/storage conditions, and less frequent dosing or smaller dosage amounts in the therapeutic, prophylactic and diagnostic use of such formulations. The invention further provides methods of utilizing the formulations of the present invention.



WO 2007/002543 A3

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/024717

## A. CLASSIFICATION OF SUBJECT MATTER

INV. C07K16/10

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C07K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, Sequence Search, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02/43660 A2 (MEDIUMMUNE INC [US]) 6 June 2002 (2002-06-06) the whole document	1-81
Y	----- DATABASE FDA [Online] Food and Drug Administration; 24 October 2003 (2003-10-24), "Synagis (Palivizumab)" XP002418333 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/LABEL/2004/103 770_S5059_LBL.PDF the whole document ----- -/--	1-52, 62-81

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

### \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

30 April 2007

Date of mailing of the international search report

01/06/2007

Name and mailing address of the ISA/

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Authorized officer

Lechner, Oskar

# INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/024717

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DATABASE FDA [Online] Food and Drug Administration; 2003, "Raptiva (Efalizumab)" XP002418334 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/APPLETTER/2003/ /125075-OLTR.PDF abstract	1-52, 62-81
Y	DATABASE FDA [Online] Food and drug administration; 1998, "HERCEPTIN (Trastuzumab)" XP002418335 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/LABEL/1998/TRA SGEN092598LB.PDF the whole document	1-52, 62-81
Y	DATABASE FDA [Online] Food and Drug Administration; June 2003 (2003-06), "Xolair (Omalizumab)" XP002418336 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/LABEL/2003/OMA LGEN062003LB.PDF the whole document	1-52, 62-81
Y	CHIRINO A J ET AL: "Characterizing biological products and assessing comparability following manufacturing changes" NATURE BIOTECHNOLOGY, NATURE PUBLISHING GROUP, NEW YORK, NY, US, vol. 22, no. 11, 4 November 2004 (2004-11-04), pages 1383-1391, XP002409409 ISSN: 1087-0156 the whole document	53-61
Y	ZIPING WEI (MEDIMMUNE; 24.07.05 2:15): "Explore the analytics of aggregation - overview of techniques for measuring protein aggregation." BARNETT INTERNATIONAL'S ASSESSING THE IMPACT OF PROTEIN AGGREGATION. CONSEQUENCES OF AGGREGATION ON DRUG DEVELOPMENT, IMMUNOLOGY, QUALITY CONTROL, AND DISEASE GENESIS. (23-24 JUNE 2005), [Online] XP002418279 Brussels Marriott. Brussels, Belgium. Retrieved from the Internet: URL:http://www.barnettinternational.com/RS C_PDFUploads//BI2020WEB.pdf> abstract	53-61

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## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/024717

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>ZIPING WEI (MEDIMMUNE; 30.07.04 09:30):  "Application of LC-MS to Characterize Protein Oxidation, Deamidation, Fragmentation and Aggregation."  THE PREMIER CONFERENCE ON THE IDENTIFICATION AND VALIDATION OF STABILITY-INDICATING AND FORCED DEGRADATION ASSAYS FOR PROTEINS. ANALYTICAL AND FORMULATION CONSIDERATIONS., [Online]  28 July 2004 (2004-07-28), - 30 July 2004 (2004-07-30) XP002418247  The Sir Francis Drake; San Francisco, CA.  Retrieved from the Internet:  URL: <a href="http://www.biologicsconsulting.com/IIR_Stab_SF_July_2004.pdf">http://www.biologicsconsulting.com/IIR_Stab_SF_July_2004.pdf</a>  abstract</p>	53-61
Y	<p>SCHUCK-P &amp; BRASWELL-EH: "Measuring protein-protein interactions by equilibrium sedimentation"  CURRENT PROTOCOLS IN IMMUNOLOGY, no. S40, 2000, page 18.8.1-18.8.22, XP002418234  the whole document</p>	53-61
A	<p>EP 1 314 437 A (CHUGAI PHARMACEUTICAL CO LTD [JP]) 28 May 2003 (2003-05-28)  the whole document</p>	1-81
A	<p>WO 2004/001007 A2 (IDEC PHARMA CORP [US]; YANG TZUNG-HORNG [US]; BACICA MICHAEL J [US]; L) 31 December 2003 (2003-12-31)  the whole document</p>	1-81
A	<p>CHEN BEI ET AL: "Influence of histidine on the stability and physical properties of a fully human antibody in aqueous and solid forms."  PHARMACEUTICAL RESEARCH (DORDRECHT), vol. 20, no. 12, December 2003 (2003-12), pages 1952-1960, XP002417746  ISSN: 0724-8741  abstract</p>	1-81
A	<p>WANG WEI: "Instability, stabilization, and formulation of liquid protein pharmaceuticals"  INTERNATIONAL JOURNAL OF PHARMACEUTICS, AMSTERDAM, NL, vol. 185, no. 2, 20 August 1999 (1999-08-20), pages 129-188, XP002323952  ISSN: 0378-5173  the whole document</p>	1-81

-/--

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/024717

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>MAHLER H-C ET AL: "Induction and analysis of aggregates in a liquid IgG1-antibody formulation"</p> <p>EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 59, no. 3, April 2005 (2005-04), pages 407-417, XP004780138</p> <p>ISSN: 0939-6411</p> <p>abstract</p>	1-81
A	<p>AHRER K ET AL: "Detection of aggregate formation during production of human immunoglobulin G by means of light scattering"</p> <p>JOURNAL OF CHROMATOGRAPHY, ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, NL, vol. 1043, no. 1, 16 July 2004 (2004-07-16), pages 41-46, XP004518349</p> <p>ISSN: 0021-9673</p> <p>the whole document</p>	1-81
A	<p>HARRIS R J ET AL: "Commercial manufacturing scale formulation and analytical characterization of therapeutic recombinant antibodies"</p> <p>DRUG DEVELOPMENT RESEARCH, NEW YORK, NY, US, vol. 61, no. 3, March 2004 (2004-03), pages 137-154, XP002324970</p> <p>ISSN: 0272-4391</p> <p>the whole document</p>	1-81
A	<p>VIDANOVIC D ET AL: "Effects of nonionic surfactants on the physical stability of immunoglobulin G in aqueous solution during mechanical agitation"</p> <p>PHARMAZIE, DIE, GOVI VERLAG, ESCHBORN, DE, vol. 58, no. 6, June 2003 (2003-06), pages 399-404, XP001247319</p> <p>ISSN: 0031-7144</p> <p>abstract</p>	1-81
A	<p>GONZALEZ M ET AL: "THERMAL STABILITY OF HUMAN IMMUNOGLOBULINS WITH SORBITOL"</p> <p>VOX SANGUINIS, S. KARGER AG, BASEL, CH, vol. 68, no. 1, 1995, pages 1-4, XP009070191</p> <p>ISSN: 0042-9007</p>	1-81
	-/--	



# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/024717

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>BACK J F ET AL: "INCREASED THERMAL STABILITY OF PROTEINS IN THE PRESENCE OF SUGARS AND POLYOLS" BIOCHEMISTRY, AMERICAN CHEMICAL SOCIETY. EASTON, PA, US, vol. 18, no. 23, 1979, pages 5191-5196, XP002261095 ISSN: 0006-2960 abstract</p>	1-81
A	<p>WO 91/16074 A (MEDIMMUNE INC [US]; JACKSON H M FOUND MILITARY MED [US]) 31 October 1991 (1991-10-31) the whole document</p>	1-81

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2006/024717

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although claims 51, 52, 78-81 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/024717

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0243660	A2	06-06-2002	AU 1994402 A	11-06-2002
			CA 2430039 A1	06-06-2002
			EP 1345625 A2	24-09-2003
			JP 2004534513 T	18-11-2004
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			JP 2005530845 T	13-10-2005
WO 9116074	A	31-10-1991	EP 0530216 A1	10-03-1993

CORRECTED VERSION

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International Bureau(43) International Publication Date  
4 January 2007 (04.01.2007)

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60/693,603 23 June 2005 (23.06.2005) US  
60/699,614 15 July 2005 (15.07.2005) US(71) Applicant (for all designated States except US): **MEDIMMUNE, INC.** [US/US]; One MedImmune Way, Gaithersburg, MD 20878 (US).

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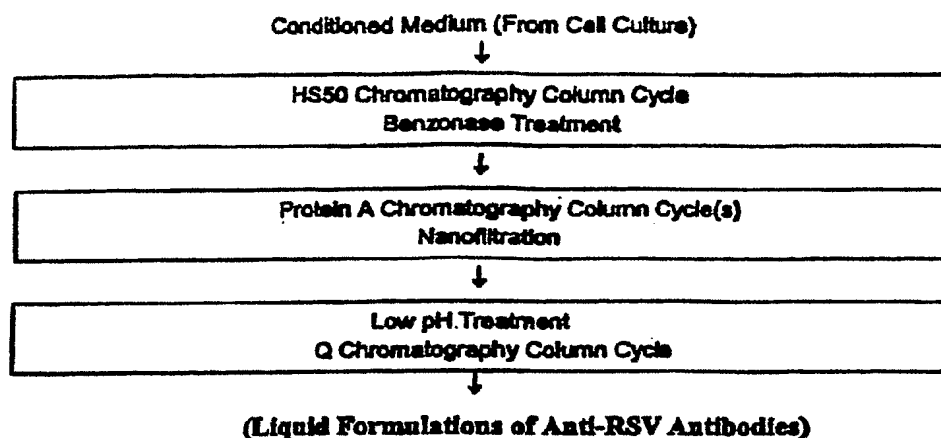
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(54) Title: ANTIBODY FORMULATIONS HAVING OPTIMIZED AGGREGATION AND FRAGMENTATION PROFILES



(57) Abstract: The present invention provides methods of optimizing the production and purification of antibody formulations that immunospecifically bind to antigens of interest and are suitable for parenteral administration to a subject, which formulations exhibit increased stability due to reduced degradation and aggregation of the antibody component on long term storage. Such methods provide formulations that offer multiple advantages over formulations produced by non-optimized methods including less stringent or more readily available transportation/storage conditions, and less frequent dosing or smaller dosage amounts in the therapeutic, prophylactic and diagnostic use of such formulations. The invention further provides methods of utilizing the formulations of the present invention.



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